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Attorney Docket: 207,388

IN THE CLAIMS:

1-21. (Cancelled)

22. (*Currently amended*) Subcutaneous implants <u>having a limited initial release of the active principle</u> and a subsequent linearly varying extended release, comprising:

- a core (i) comprising at least one active principle dispersed in a polymeric matrix essentially consisting of PLGA obtained by extrusion, wherein said active principle is at most 55% mass/mass of the total weight of the core,

- a coating (ii) in film form comprising as the main component PLGA, said PLGA having a molecular weight between 50,000 and 150,000 and a molar ratio of lactic acid to glycolic acid monomers between 50:50 and 95:5.

-said implants having an extended overall-release of the active principle with a linear profile.

- 23. (*Previously presented*) Subcutaneous implant as claimed in claim 22, wherein the active principle contained in the core (i) is selected from the group consisting of a peptide, an active principle able to increase bone density selected from pharmaceutically acceptable bisphosphonic acids and their salts, vitamin D or analogues thereof and sex hormones, an analgesic-narcotic, a steroid hormone for hormonal treatments during menopause or for contraception.
- 24. (*Previously presented*) Subcutaneous implant as claimed in claim 23, wherein the core (i) contains a peptide the particles of said active principle present heterogeneous dimensions which vary from 1 micron to 63 microns.
- 25. (*Previously presented*) Subcutaneous implants as claimed in claim 22, wherein the PLGA used in the core (i) presents a molecular weight between 50,000 and 150,000 and a molar ratio of lactic acid to glycolic acid monomers between 50:50 and 95:5.
- 26. (Previously presented) Subcutaneous implants as claimed in claim 22, wherein the coating (ii) contains PLGA in amounts ranging from 75 to 99,999% and the

remaining to 100% consisting essentially of excipients and/or of the same active ingredient used in the core (i).

- 27. (Cancelled)
- 28. (*Previously presented*) The subcutaneous implants according to claim 26, wherein the coating (ii) consists of a mixture of 80% PLGA and the remaining to 100% of at least one hydrophilic excipient.
- 29. (*Previously presented*) The subcutaneous implants according to claim 28, wherein said hydrophilic excipient is selected from the group consisting of polyvinyl pyrrolidone, D-mannitol and mixtures thereof.
- 30. (Withdrawn) The subcutaneous implants according to claim 26, wherein the coating (ii) consists of a mixture of 75% PLGA and the remaining to 100% of the same active ingredient contained in the core (i).
- 31. (*Previously presented*) Subcutaneous implant as claimed in claim 22, wherein said coating in film form (ii) consists of PLGA with a molecular weight between 50,000 and 150,000 and a molar ratio of lactic acid to glycolic acid monomers between 50:50 and 95:5.
- 32. (*Previously presented*) Subcutaneous implant as claimed in claim 31, wherein said PLGA presents an average molecular weight between 100,000 and 150,000 and said molar ratio is between 50/50 and 75/25.
- 33. (*Previously presented*) Subcutaneous implant as claimed in claim 22, wherein the coating (ii) presents a thickness between 5 and 250 μm.
- 34. (*Previously presented*) Subcutaneous implant as claimed in claim 33, wherein said thickness is between 10 and 100 μ m.
- 35. (Withdrawn) Process for preparing the subcutaneous implants as claimed in claim 22, comprising the following stages:
 - a) preparing the core (i) containing the active principle by extrusion;

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b) passing the core (i) into a solution of PLGA in a suitable solvent selected from the group consisting of apolar and aprotic polar solvents such that said cores remain in contact with said solution for a period between 1 and 5 seconds; and

- c) drying said cores originating from stage (b).
- 36. (Withdrawn) Process as claimed in claim 35, wherein the polar solvent is a chlorinated solvent.
- 37. (Withdrawn) Process as claimed in claim 36, wherein said solvent is methylene chloride.
- 38. (Withdrawn) Process as claimed in claim 35, wherein said aprotic polar solvent is selected from the group consisting of acetonitrile, ethyl acetate, and tetrahydrofuran.
- 39. (Withdrawn) Process as claimed in claim 35, wherein the PLGA concentration in the solution used in stage (a) is comprised between 70 and 300 g/l.
- 40. (Withdrawn) Process as claimed in claim 39, wherein said concentration is comprised between 100 and 200 g/l.
- 41. (Withdrawn) Process as claimed in claim 35, wherein said contact time is 1 second.
- 42. (Withdrawn) Process for preparing the subcutaneous implant according to claim 22 comprising the following stages:
 - a') mixing the active principle with PLGA,
- b') possibly granulating the mixture originating from (a') in the minimum solvent quantity, and drying the granules obtained,
- c') co-extruding the mixture originating from (a') or from (b') together with the PLGA used for preparing the coating in film form (ii).